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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,413	03/26/2004	Hsing-Wen Sung	S&T-134	3273

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EXAMINER	
KENNEDY, SHARON E	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,413	SUNG ET AL.	
	Examiner	Art Unit	
	Sharon E. Kennedy	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 26 March 2004 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 03/26/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: In Figure 9, the examiner cannot find support for "I" in the specification. This clearly represents the interface. Despite the presence of the form paragraph below, applicant may instead correct the specification to indicate that "I" is the interface. Or, applicant could change "I" to --27-- as in Figure 10.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 (01/10/2005 version) of copending Application No. 10/520,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims is directed to a biodegradable stent having at least one zone of a biodegradable material which is crosslinked with the same "biological materials". For example, claim 1 of '878 encompasses instant claim 7.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 (08/11/2004 version) of copending Application No. 10/916,170. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims is directed to a biodegradable stent having at least one zone of a biodegradable material which is crosslinked with the same "biological materials". For example, claim 1 of '170 encompasses instant claim 7.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8-14, 19, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Buscemi et al., US 5,464,450. Applicant does not describe the spatial relationship of the zones in claim 1, accordingly, the claims are anticipated. The claimed "first biodegradable material" which is a supporting material can be interpreted to be main body 11. The claimed "second therapeutic zone comprising a second biodegradable material" can be film 32 or fibers 18. See especially column 5, lines 10-37. Regarding the claimed bioactives, see the lists of drugs in column 6. Regarding claim 8, the applicant's disclosure has been carefully examined to discern the meanings of "biological material" and "solidifiable substrate". Applicant states in [0004] that this includes collagen, which is disclosed by Buscemi at column 6, lines 13-14. Buscemi states that the biodegradable materials may be collagen or other connective proteins or natural materials, co-polymers, composites and combinations thereof with other biodegradable polymers. Regarding claim 10, Buscemi discloses polyglycolic acid (column 5, line 13), which is a polyhydroxy acid. Regarding claim 13, see column 6, line 18, "methotrexate". Regarding claim 14, see column 6, line 16, "aspirin". Regarding claim 19, see column 6, line 26, "growth factors". Regarding claim 20, careful note is made of applicant's discussion in paragraph [0207] regarding vulnerable plaques, etc.

Buscemi states the stent is useful to support post angioplasty vessels (column 1, lines 10-23). Since applicant does not recite anything in the structure of the stent which distinguishes from Buscemi, such as a specific drug and release profile, the examiner takes the position that since Buscemi uses the stent in the same environment as applicant, then Buscemi inherently treats these types of plaques as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi '450 in view of Buirge et al., US 5,693,085. Buscemi discloses all of the claimed embodiments including the use of collagen as a biodegradable material. Buscemi does not disclose how the collagen is prepared. Buirge exemplifies that it is

known in the art to crosslink collagen material used in stents claimed for the purpose of controlling the characteristics of the collagen. Accordingly, it would be obvious to one of ordinary skill in the art to crosslink the Buscemi collagen materials as necessary as taught by Buirge to control the characteristics of the stent.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi '450 in view of Lee et al., US 6,806,257. Buscemi discloses all of the claimed embodiments except for the specific bioactive agent. In column 6, Buscemi plainly states that many types of useful drugs may be incorporated into the stent. Lee is cited to exemplify that it is known in the art to use drugs such as claimed by applicant, specifically, flavones, for the purpose of reducing inflammation in mammals (abstract), and that these flavones may be delivered by incorporating the drug into an intracoronary stent (column 19, line 17). Accordingly, it would be obvious to one of ordinary skill in the art to apply flavones, etc., to the Buscemi stent for the purpose of reducing inflammation in view the Buscemi suggestion, teaching and motivation.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi '450 in view of Bisgaier et al., US 2003/0109442. Buscemi discloses all of the claimed embodiments except for the specific bioactive agent. In column 6, Buscemi plainly states that many types of useful drugs, including genetic materials (column 6, line23) may be incorporated into the stent. Bisgaier is cited to exemplify that it is known in the art to use drugs such as claimed by applicant, specifically, ApoA-I, for the purpose of gene delivery for preventing restenosis (abstract), and that these may be delivered by applying the drug to an intracoronary stent ([0067]+). Accordingly, it would be obvious

to one of ordinary skill in the art to apply and ApoA-I, etc., to the Buscemi stent for the purpose of reducing inflammation in view of the Buscemi suggestion, teaching and motivation.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buscemi '450 in view of Itescu, US 2005/0233992. Buscemi discloses all of the claimed embodiments except for the specific bioactive agent. In column 6, Buscemi plainly states that many types of useful drugs, genes, etc., may be incorporated into the stent. Itescu is cited to exemplify that it is known in the art to use endothelial progenitor cells as claimed by applicant, for the purpose of inducing neovascularization (abstract), and that these may be delivered locally by applying the drug to an intracoronary stent ([0088]). Accordingly, it would be obvious to one of ordinary skill in the art to apply endothelial progenitor cells, etc., to the Buscemi stent for the purpose of reducing inflammation in view of the Buscemi suggestion, teaching and motivation.

Allowable Subject Matter

Claims 3, 5 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and if terminal disclaimers as suggested above were filed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

/Sharon E. Kennedy/
Sharon E. Kennedy
Primary Examiner
Art Unit 1615